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UNITED STATES DISTRICT COURT FOR THE

EASTERN DISTRICT OF CALIFORNIA

SACRAMENTO DIVISION

ANGELE NELSON, individually and on behalf of all others similarly situated, Plaintiff, v. AMAG PHARMACEUTICALS, INC., Defendant.	Case No. _____ **CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL**

Plaintiff ANGELE NELSON brings this case on behalf of herself and all others similarly situated (the "Class," defined below) against defendant AMAG PHARMACEUTICALS, INC., and in support thereof states:

NATURE OF THE CASE

1. This case arises from Defendant's marketing, sale, and manufacturing of the drug Makena, a hydroxyprogesterone caproate.

PARTIES & BACKGROUND

2. ANGELE NELSON is a California citizen residing in Yuba City, Sutter County, California. During the class period (as defined below), Ms. Nelson was prescribed, injected with, and purchased Makena. Ms. Nelson paid out of pocket for Makena. The Makena shots cost at least hundreds of dollars per shot.

3. Defendant AMAG PHARMACEUTICALS, INC. ("AMAG") is a Delaware corporation headquartered in Waltham, Massachusetts. AMAG is a publicly traded company. (Nasdaq: AMAG). AMAG currently holds the exclusive rights to Makena.

4. Hologic, Inc. ("Hologic") is a Delaware corporation, headquartered in Marlborough, Massachusetts. Hologic (NASDAQ: HOLX) is a multinational, publicly-traded corporation. Hologic developed and originally held the exclusive rights to Makena. Hologic sold the exclusive rights to Makena to KV Pharmaceutical shortly after Hologic obtained FDA approval in early 2011.

5. Lumara Health, Inc., f/k/a KV Pharmaceutical Co., ("Lumara") was a Missouri corporation, headquartered in St. Louis, Missouri. KV Pharmaceutical purchased the rights to Makena from Hologic Inc. KV Pharmaceutical and subsequently Lumara manufactured and sold Makena during the class period. AMAG acquired Lumara in 2014, including the exclusive rights to manufacture and sell Makena.

6. KV Pharmaceutical came under fire in 2009 when the Justice Department filed lawsuits against KV Pharmaceutical and several of its executives for violating the Food, Drug and Cosmetic Act by manufacturing and selling oversized morphine tablets that contained more morphine than the label stated.[1]

7. In March 2011, KV Pharmaceutical CEO Mark Hermelin pled guilty to misbranding and

[1] Former Drug Company Executive Pleads Guilty in Oversized Drug Tablets Case, U.S. Department of Justice (March 10, 2011), https://www.justice.gov/opa/pr/former-drug-company-executive-pleads-guilty-oversized-drug-tablets-case.

received thirty days in jail, along with a fine of $1,000,000 and a forfeiture of $900,000.[2] However, Hermelin fled to Israel once a federal investigation was opened into the company's practices. The charging U.S. attorney stated that felony charges would have been brought against Hermelin but for the fact that Israel may not have extradited Hermelin unless the charges were reduced.[3]

8. After this debacle, KV Pharmaceutical was forced to file for chapter 11 bankruptcy and re-emerged under the name Lumara Health in 2013.[4]

9. Lumara Health continued to manufacture, market, and sell Makena.

10. In 2014, AMAG bought Lumara for $675 million and an additional $350 million contingent on sales milestones.[5] The flagship product in the acquisition was Makena.

JURISDICTION AND VENUE

11. Venue is proper in this District under 28 U.S.C. § 1391(b) because at all times relevant to the Complaint: (a) AMAG transacted business, was found, or acted through subsidiaries or agents present in this District; and (b) a substantial part of the events giving rise to Plaintiff's claims occurred in this District. Alternatively, venue lies under 28 U.S.C. § 1391(c) because AMAG is subject to the Court's personal jurisdiction.

12. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(d) because the case is a class action, the class members are diverse from AMAG, and the amount in controversy exceeds $5,000,000.

13. This Court has personal jurisdiction over AMAG because AMAG transacted business in this District.

FACTUAL ALLEGATIONS

I. History of Hydroxyprogesterone Caproate and Makena

14. The hormonal medication hydroxyprogesterone caproate has been in the U.S. marketplace

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[2] *Id.*

[3] Ex-chief of KV Pharmaceutical gets month or less in jail, Jim Doyle, St. Louis Post Dispatch (March 11, 2011) available at https://www.stltoday.com/business/local/ex-chief-of-kv-pharmaceutical-gets-month-or-less-in/article_693616ab-1af6-5d34-a763-6fd01683aa5c.html.

[4] Angela Mueller, *Former KV Pharmaceutical to be Acquired*, St. Louis Business Journal (2014), https://www.bizjournals.com/stlouis/blog/health-care/2014/09/former-kv-pharmaceutical-to-be-acquired.html.

[5] Grogan, *AMAG $1 Billion Deal to Buy Preterm Birth Drug Makena*.

since 1956. Over time, the pharmaceutical companies have not added anything new to this drug—failing to make the drug a viable product for mothers at risk of premature births and failing to mitigate the potential adverse consequences of taking hydroxyprogesterone caproate. The only real addition by the manufacturers has been an enormous price increase.

15. Shering AG developed hydroxyprogesterone caproate in 1953 and reported its medical effects in 1954.[6] The drug was first marketed in Japan in 1954 and 1955 before it was introduced in the United States in 1956 by Squib, having acquired the license to the patent, under the brand name Delalutin to manage abnormal bleeding in patients with uterine cancer.[7]

16. In the 1960s, Delalutin began to be used to treat pregnant women who had tumorous ovaries removed.[8]

17. In the 1990s, Delalutin (and thus hydroxyprogesterone caproate) had become a leading drug to treat an imminent premature birth threat during pregnancy after studies focused on its potential to reduce preterm births.[9]

18. Bristol Meyer Squibb voluntarily withdrew the drug from the market in 1999.[10]

19. Interest in hydroxyprogesterone caproate resurged after a taxpayer-funded study appeared to find that the drug reduced the risk of preterm births in at-risk mothers.[11] It was only after this study was published that KV Pharmaceutical acquired hydroxyprogesterone caproate (via the drug Makena)

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[6] Ralph I. Dorfman, *Methods in Hormone Research*, Academic Press (1966).

[7] Lippincott, *New and Nonofficial Drugs*, Council on Drugs (1964); *see also* Tom Morrow, MD, *Resurrection of Preterm Labor Drug Evokes Questions of Fairness*, Biotechnol. Healthc. 2011, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3138388/.

[8] Macintyre, *Ovarian surgery with loss of corpus luteum in early pregnancy. Report of two cases brought to term with progestin (Delautin) therapy*, Can. Med. Assoc. J. (1961), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1848126/pdf/canmedaj00899-0006.pdf.

[9] Keirse, Progestogen administration in pregnancy may prevent preterm delivery, Obstet. Gynaecol. (Feb. 1990); *see also* Morrow, *Resurrection of Preterm Labor Drug Evokes Questions of Fairness.*

[10] *Determination that Delalutin Injection, 125 mg/ mL and 25 mg/ mL, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness*, FDA (June 25, 2010), https://www.federalregister.gov/documents/2010/06/25/2010-15416/determination-that-delalutin-hydroxyprogesterone-caproate-injection-125-milligramsmilliliter-and-250.

[11] Meis PJ, Klebanoff M, Thom E, Dombrowski MP, Sibai B, Moawad AH, et al, *Prevention of Recurrent Preterm Delivery By 17 Alpha-Hydroxyprogesterone Caproate*, New England Journal of Medicine (June 2013), 348(24):2379-2385, https://www.nejm.org/doi/full/10.1056/NEJMoa035140.

and its exclusive marketing rights.[12]

II. Makena Receives FDA Fast-Track Approval

20. FDA fast-track approval was created to expedite the development and review of drugs that treat serious conditions and fill an unmet medical need.[13]

21. The "New Drug Application" or NDA seeking accelerated approval for Makena was approved by the FDA on February 3, 2011.[14]

22. However, the data used to support Makena's fast-track application and subsequent approval was insufficient to make a proper determination of the risks of Makena.[15]

23. The FDA relied heavily on a single clinical trial published in 2003 by the National Institute of Child Health and Human Development ("NICHD").[16] However, the government's Statistical Review and Evaluation found that reliance solely on the 2003 NICHD study was insufficient to establish the efficacy of the drug in preventing preterm births.[17]

24. Analysis of the NICHD trial found that: 1) the study failed to identify the optimal time to start taking Makena; 2) one study center accounted for nearly half of the subjects, calling into question the effectiveness of the study's randomizations; and 3) women treated with Makena experienced fetal and neonatal deaths earlier than women who were taking the placebo.[18]

25. The statistical review concluded that Makena's medical benefits in reducing preterm

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[12] Food and Drug Administration, Accelerated Approval Letter for New Drug Application 21945 (Feb. 3, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/021945s000ltr.pdf.

[13] Fast Track, FDA (current as of Jan. 4, 2018), https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track.

[14] Food and Drug Administration, Accelerated Approval Letter for New Drug Application 21945 (Feb. 3, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/021945s000ltr.pdf.

[15] Jim Doyle, *FDA's Fast-Track Approval of Makena Could Backfire on KC*, St. Louis Post-Dispatch (Mar. 13, 2011), https://www.stltoday.com/business/local/fda-s-fast-track-approval-of-makena-could-backfire-on/article_e4472916-0646-539d-b04a-520756765418.html.

[16] Meis PJ, Klebanoff M, Thom E, et al., *Prevention of Recurrent Preterm Delivery By 17 Alpha-Hydroxyprogesterone Caprote*, N Eng J Med. (June 2013), 348(24):2379-2385, https://www.nejm.org/doi/full/10.1056/NEJMoa035140.

[17] Statistical Review and Evaluation: Clinical Studies (21-945 Makena), Food and Drug Administration (July 13, 2010), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/021945Orig1s000StatR.pdf.

[18] *Id*. at 6.

births were "**not convincing** when considering that only one study was submitted to support the claim of effectiveness" for hydroxyprogesterone caproate.[19]

26. Despite the FDA's own statisticians' misgivings about the effectiveness of Makena, the FDA approved it on a fast-track basis, allowing the drug to hit the U.S. market shortly thereafter.[20]

27. The fast-track approval was conditioned on a follow-up, long-term clinical trial to confirm the effectiveness of hydroxyprogesterone caproate in preventing preterm births.[21]

28. On March 8, 2019, after 8 years of Makena sales at absurdly-high prices, AMAG announced the results of that FDA-mandated follow-up trial, known as the PROLONG (Progestin's Role in Optimizing Neonatal Gestation) study ("PROLONG Study").

29. According to AMAG, the PROLONG Study's results showed no "statistically significant difference between the treatment [Makena] and placebo arms for the co-primary endpoints." The results also showed there was no significant difference between subjects using Makena and subjects using placebos on the rate or neonatal mortality or morbidity. [22] In other words, the PROLONG Study showed that Makena, is no more effective than a placebo.

30. On October 29, 2019, and based on the results of the PROLONG Study, the FDA Bone, Reproductive and Urologic Drugs Advisory Committee recommended that Makena be withdrawn from the market.[23]

31. On information and belief, AMAG knew far earlier than finalization of the PROLONG Study that Makena was ineffective.

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[19] *Id*. at 39.

[20] Food and Drug Administration, Accelerated Approval Letter for New Drug Application 21945 (Feb. 3, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/021945s000ltr.pdf.

[21] *Id*.

[22] Amag Pharmaceuticals Announces Topline Results from the Prolong Trial Evaluating Makena, AMAG Pharamceuticals (March 8, 2019), https://www.amagpharma.com/news/amag-pharmaceuticals-announces-topline-results-from-the-prolong-trial-evaluating-makena-hydroxyprogesterone-caproate-injection.

[23] Sumanthi Reddy, *FDA Committee Recommends Withdrawing Treatment to Prevent Preterm Births From Market*, The Wall Street Journal; (Oct. 29, 2019), https://www.wsj.com/articles/fda-committee-recommends-withdrawing-treatment-to-prevent-preterm-births-from-market-11572387799.; *see also* Ned Pagliarulo, *FDA Panel Backs Withdrawal of AMAG Drug to Prevent Preterm Birth*, BiopharamaDive (Oct. 30, 2019), https://www.biopharmadive.com/news/amag-makena-fda-advisory-panel-vote-withdrawal-preterm-birth/566159/.

32. The PROLONG Study included approximately 1,700 pregnant women and examined the efficacy of Makena versus a placebo in preventing preterm births in women who had a history of spontaneous preterm births. The study was a randomized, double-blinded, placebo-controlled clinical trial. [24]

33. According to AMAG, 11% of the women in the study who took Makena delivered their babies at 35 weeks or earlier; whereas 11.5% of women who took the placebo delivered their babies at 35 weeks or earlier. There were also no statistically significant differences concerning miscarriages and stillbirths (adverse events) between Makena and the placebo treatment.[25]

34. From AMAG's own statements, the PROLONG Study demonstrated Makena was essentially as effective as a placebo.

35. Currently, the FDA has not yet removed Makena from the U.S. market.

36. AMAG reported that its 2018 revenue for operations was approximately $474 million, with Makena contributing the lion's share of AMAG's annual revenue at $323 million.[26]

III. Makena Is Marketed to Women as a Drug to Prevent Preterm Births

37. Makena was and is marketed as an effective hormonal medication that reduces the risks for pregnant mothers of giving birth before term.[27]

38. Makena's website explicitly states: "Makena helps you get closer to term"; "Makena…is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past"; and "Makena gives moms an extra layer of support."[28]

39. AMAG's marketing targets mothers with testimonials of how effective its product was for

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[24] AMAG Pharmaceuticals Announces Topline Results from the Prolong Trial Evaluating Makena, AMAG Pharmaceuticals (Mar. 8, 2019).

[25] *Id.*

[26] AMAG Reports Fourth Quarter and Full Year 2018 Financial Results and Provides Company Update, AMAG Pharmaceuticals (Feb. 7, 2019), https://www.amagpharma.com/news/amag-reports-fourth-quarter-and-full-year-2018-financial-results-and-provides-company-update/.

[27] *Reducing Risk with Makena Auto-Injector*, Makena (hydroxyprogesterone caproate injection), https://makena.com/reducing-preterm-birth-risk-with-makena/.

[28] *Id.*

other moms, including one mother stating that "receiving the weekly injections of Makena is giving me the peace of mind knowing that I'm doing everything I can to help prolong this pregnancy" and another mother saying, "looking back, Makena gave me hope that I had a better chance of delivering Olivia full term."[29]

40. Makena's patient education brochure extols Makena as an effective drug for mothers who had a previous preterm birth and are at risk for another preterm delivery. The front of the brochure reads "HELP GIVE YOUR BABY MORE TIME TO DEVLEOP."[30] The brochure tells mothers that "Makena…helps give bab[ies] more time to develop."[31] The pamphlet ends by reminding mothers that "Every week counts when you're pregnant."[32]

41. But for such statements and but for AMAG's material omissions, Plaintiff and class members would not have purchased and been injected with Makena.

IV. Makena Is Exorbitantly Priced

42. In 2008, Hologic, who owned the rights to Makena, and KV Pharmaceutical entered into an agreement giving KV Pharmaceutical worldwide rights to manufacture, market, and sell Makena.[33]

43. KV Pharmaceutical abused its rights under the Orphan Drug Act,[34] a law passed to attract pharmaceutical companies to research and develop drugs designed to treat rare but serious conditions like ALS, Tourette syndrome, muscular dystrophy, etc.[35]

44. The Orphan Drug Act allows drug companies, like KV pharmaceutical, exclusive

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[29] *Id.*

[30] Makena Patient Education Brochure (English), Makena (hydroxyprogesterone caproate injection), https://makena.com/wp-content/themes/MakenaDTP/file/Makena_Auto-Injector_Patient_Education_Brochure_-_English.pdf.

[31] *Id.*

[32] *Id.*

[33] Lisa Brown, *KV Pharmaceutical, hologic Settle Makena Dispute*, St. Louis Post-Dispatch (Dec. 13, 2012), https://www.stltoday.com/business/local/kv-pharmaceutical-hologic-settle-makena-dispute/article_79fd8d56-bd16-51fe-9225-a6ac33d8ba8a.html.

[34] 21 U.S.C.A. § 360cc (Orphan Drug Act).

[35] Richard Knox, *Premeire Prevention Drug Costs 53 Times More Than Generic, But Researches Find it's No Better*, WBUR 90.9 (Oct. 3, 2017), https://www.wbur.org/commonhealth/2017/10/03/preterm-birth-prevention-drug-costs (Knox Report).

marketing rights for a drug that treats a rare disease or condition for up to seven years.[36] Makena was designated as an "orphan drug" under the Act in 2007, thereby granting KV Pharmaceutical the ability to sell Makena at expensive prices.[37]

45. Makena hit the market with a breathtaking sticker price: $1,500 per injection, up from the generic $10-$20 price. Women who were taking the generic drug were understandably shocked: "I'm ready to have a heart attack," Janice Watkins, who had been taking the generic drug known as 17P, said in 2011 after she learned of the price increase from her doctor's office.[38] "I'm nervous now because I have to go home and call my insurance company to see if they'll cover me."[39]

46. Due to public outrage over KV Pharmaceutical's expected price hike, the FDA allowed compounding pharmacies to make the drug in their pharmacies in order to allow a more affordable option for mothers.[40]

47. As reported at the time, KV Pharmaceutical was only the manufacturer and did nothing to discover Makena or research the drug.[41]

48. Eventually, KV Pharmaceutical reduced the price to $690 per Makena injection.[42]

49. Although compounding pharmacies may offer hydroxyprogesterone caproate at a lower price than AMAG, these specialized pharmacies do not offer a viable alternative for at-risk pregnant women.

50. Compounding pharmacies are less regulated and there is a greater potential for error when

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[36] 21 U.S.C.A. § 360cc (Orphan Drug Act).

[37] Knox Report.

[38] https://www.post-gazette.com/news/health/2011/03/11/Pregnancy-drug-s-sharp-price-hike-called-greed/stories/201103110343.

[39] David Whelan, Forbes, "Is KV Pharmaceutical A Flat-Out Evil Company?" available at https://www.forbes.com/sites/davidwhelan/2011/03/11/is-kv-pharmaceutical-a-flat-out-evil-company/#11da813831b5.

[40] Alexander Gaffney, *FDA Maintains Compounding Exemption for KV Pharmaceutical's Makena,* Regulatory Focus (June 18, 2012), https://www.raps.org/regulatory-focus/news-articles/2012/6/fda-maintains-compounding-exemption-for-kv-pharmaceuticals-makena.

[41] David Whelan, Forbes, "Is KV Pharmaceutical A Flat-Out Evil Company?"

[42] *Id; see also* Senator Sherrod Brown Statement on Makena Repricing.

creating compounded formulations of drugs in these pharmacies.[43]

51. In fact, the FDA cited a compounding pharmacy in 2014 for making tainted batches of hydroxyprogesterone caproate due to unsanitary conditions.[44]

52. Further, doctors and pharmacy directors often fear the repercussions of prescribing a compounded hydroxyprogesterone caproate over an FDA-approved product, because any unforeseen side effect due to the compounded drug could result in liability for the medical professional or pharmacist.[45]

53. Since AMAG acquired Lumara in 2014, AMAG has continued price-gouging its customers.

54. As one woman recently reported: "Insanely expensive - did not find this out until half way through my amount of injections that they were charging my insurance $1500 per shot! Insurance "covered" half leaving me with $750ish a shot. No one told me they would be this expensive. Hopefully I can save someone the surprise. I get them in the hip alternating sides each time. Some days it hurts others it doesn't I think it really depends on who is administering."[46]

CLASS ACTION ALLEGATIONS

55. Plaintiff brings this class action under California law and Fed. R. Civ. P. 23 (the "Class"):

> All persons who were prescribed and injected with Makena in the State of California from January 1, 2011 to the present (the "Class Period").

Excluded from the Class are Defendant, its parents, subsidiaries and affiliates, its directors and officers and members of their immediate families; also excluded are any federal, state, or local governmental entities, any judicial officers presiding over this action and the members of their immediate family and judicial staff, and any juror assigned to this action.

56. Members of the Class are so numerous that their individual joinder herein is impracticable. On information and belief, Class members number at least in the hundreds, if not thousands. The precise

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[43] Yesha Patel, PharmD, *Makena or Compounded 17P?*, Pharmacy and Therapeutics (Sept. 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3462605/.

[44] Eric Palmer, *FDA Cites Compounder for Making Tainted Version of KV's Makena*, FiercePharma (Mar. 14, 2014), https://www.fiercepharma.com/regulatory/fda-cites-compounder-for-making-tainted-version-of-kv-s-makena.

[45] *Id.*

[46] Comment posted Sept. 18, 2019, https://www.drugs.com/comments/hydroxyprogesterone/makena.html (accessed Oct. 30, 2019).

number of Class members and their identities are unknown to Plaintiffs at this time but will be determined through discovery. Class members may be notified of the pendency of this action by publication and/or mailing through Defendant's sales records.

57. Common questions of law and fact exist as to all Class members and predominate over questions affecting only individual Class members. Common legal and factual questions include, but are not limited to:

a. whether AMAG was unjustly enriched by its conduct;

b. whether AMAG advertised or marketed Makena in a way that was false or misleading;

c. whether Makena failed to conform to the representations, which were published, disseminated, and advertised by AMAG to Plaintiff and the Class;

d. whether AMAG concealed from Plaintiff and the Class that Makena did not conform to its stated representations;

e. whether, by the misconduct set forth in this Complaint, AMAG has engaged in unfair, fraudulent, or unlawful business practices with respect to the advertising, marketing, and sales of Makena;

f. whether AMAG violated the UCL; and

g. whether, as a result of AMAG' misconduct as alleged herein, Plaintiff and the Class members are entitled to restitution, injunctive, and/or monetary relief and, if so, the amount and nature of such relief.

58. Plaintiff's claims are typical of the claims of the Class members as all Class members are similarly affected by AMAG's wrongful conduct. Plaintiff has no interests antagonistic to the interests of the other Class members. Plaintiff and all Class members have sustained economic injury arising out of AMAG's violations of law as alleged herein.

59. Plaintiff is an adequate representative of the Class because her interests do not conflict with the interests of the Class members she seeks to represent. Plaintiff has retained counsel competent and experienced in prosecuting class actions. The interests of Class members will be fairly and adequately protected by Plaintiff and her counsel.

60. The class mechanism is superior to other available means for the fair and efficient adjudication of the claims of Plaintiff and Class members. Each Class member may lack the resources to undergo the burden and expense of individual prosecution of the complex and extensive litigation necessary to establish AMAG's liability. Individualized litigation increases the delay and expense to all

parties and multiplies the burden on the judicial system presented by the complex legal and factual issues of this case. Individualized litigation also presents a potential for inconsistent or contradictory judgments. In contrast, the class action device presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court on the issue of AMAG's liability. Class treatment of the liability issues will ensure that all claims and claimants are before this Court for consistent adjudication of the liability issues.

COUNT I: VIOLATION OF THE CALIFORNIA BUS. & PROF. CODE § 17200

61. Plaintiff re-alleges the allegations above as if fully set forth herein.

62. Plaintiff brings this claim on behalf of herself and the Class under the California Bus. & Prof. Code § 17200 *et seq.*

63. In connection with the sale and advertisement of Makena, AMAG misrepresented Makena's effectiveness at preventing preterm births.

64. AMAG's statements that Makena was effective in reducing preterm births constitute unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising in violation of the California Unfair Competition Law.

65. These falsities include but are not limited to AMAG's statements that:

a. "Makena helps you get closer to term."

b. "Makena … is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past."

c. "Makena gives moms an extra layer of support."

d. "receiving the weekly injections of Makena is giving me the peace of mind knowing that I'm doing everything I can to help prolong this pregnancy."

e. "looking back, Makena gave me hope that I had a better chance of delivering Olivia full term."

f. "Makena … helps give bab[ies] more time to develop."

Each of these statements was false and deceptive and constituted acts or practices prohibited by California Bus. & Prof. Code § 17200

66. Plaintiff and all Class members suffered an ascertainable loss caused by AMAG's

misrepresentations because Plaintiff and Class members paid a premium price for Makena when the product was worth zero or close to zero based on its actual attributes.

67. Additionally, Plaintiff and the class suffered ascertainable losses of money and property by virtue of having to undergo weekly injections of a drug that did not work, including all the wasted time associated with taking such injections.

68. As a result of AMAG's unlawful, unfair or fraudulent business practices, AMAG has reaped unfair benefits and illegal profits at the expense of Plaintiff and the Class. AMAG should thus be made to disgorge its ill-gotten gains and restore such monies to Plaintiff.

69. Under California Business and Professions Code § 17203, Plaintiffs and class members seek such orders or judgments as may be necessary to prevent the AMAG's future use of its unlawful, unfair or fraudulent practices, and to restore to Plaintiff and the Class any money or property that may have been acquired by means of AMAG's unfair competition

70. AMAG's unlawful, unfair or fraudulent business practices entitle Plaintiff to seek preliminary and permanent injunctive relief, including but not limited to orders that AMAG account for, disgorge and restore to Plaintiff and the Class its unlawfully obtained gains.

COUNT II: CALIFORNIA CONSUMER'S LEGAL REMEDIES ACT

71. Plaintiff re-alleges the allegations above as if fully set forth herein.

72. Plaintiff brings this claim on behalf of herself and the Class under the California Consumer Legal Remedies Act (CLRA), Cal. Civ. Code § 1770 *et seq.*

73. In connection with the sale and advertisement of Makena, AMAG misrepresented Makena's effectiveness at preventing preterm births.

74. AMAG's statements that Makena was effective in reducing preterm births constitute unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising in violation of the CLRA.

75. These falsities include but are not limited to AMAG's statements that:

a. "Makena helps you get closer to term."

b. "Makena … is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past."

c. "Makena gives moms an extra layer of support."

d. "receiving the weekly injections of Makena is giving me the peace of mind knowing that I'm doing everything I can to help prolong this pregnancy."

e. "looking back, Makena gave me hope that I had a better chance of delivering Olivia full term."

f. "Makena … helps give bab[ies] more time to develop."

Each of these statements was false and deceptive and constituted acts or practices prohibited under the CLRA.

76. Plaintiff and all Class members suffered an ascertainable loss caused by AMAG's misrepresentations because Plaintiff and Class members paid a premium price for Makena when the product was worth zero or close to zero based on its actual attributes.

77. Additionally, Plaintiff and the Class suffered ascertainable losses of money and property by virtue of having to undergo weekly injections of a drug that did not work, including all the wasted time associated with taking such injections.

78. As a result of AMAG's unfair business practices, AMAG has reaped unfair benefits and illegal profits at the expense of Plaintiff and the Class. AMAG should thus be made to disgorge its ill-gotten gains and restore such monies to Plaintiff.

79. Under Cal. Civ. Code § 1780, Plaintiffs and class members seek such orders or judgments as may be necessary to prevent AMAG's future use of its unfair and unlawful practices, for their actual damages, for an order enjoining the unlawful conduct identified herein, for restitution, attorney fees and costs, and for any other relief the court deems proper.

80. AMAG's unfair business practices entitle Plaintiff to seek preliminary and permanent injunctive relief, including but not limited to orders that AMAG account for, disgorge and restore to Plaintiff its unlawfully obtained gains.

COUNT III: UNJUST ENRICHMENT

81. Plaintiff re-alleges the allegations above as if fully set forth herein.

82. Plaintiff and the Class members conferred a benefit on AMAG by purchasing Makena.

83. AMAG has benefited and knows it has benefitted at Plaintiff's and the Class members'

expense by the sale of the product by collecting the price of the falsely represented product, which consumers paid because of AMAG's deceptive and misleading advertising and representations and/or omissions.

84. AMAG's retention of the revenues from Plaintiff and Class members' purchases of Makena, under these circumstances, is unjust and inequitable because consumers were misled by AMAG to believe that they were receiving a product effective at preventing preterm births when it was not.

85. Plaintiff and Class members were injured because they purchased a product, they otherwise would not have purchased, due to AMAG's falsities, misrepresentations, and/or omissions.

86. Because AMAG's retention of the non-gratuitous benefit conferred on it by Plaintiff and the Class members is unjust and inequitable, AMAG must pay restitution to Plaintiff and the Class members, as ordered by the Court.

PRAYER FOR RELIEF

Plaintiff, on behalf of herself and the Class members, requests relief as follows:

A. That the Court determine that this action may be maintained as a class action under Rule 23(a) & (b) of the Federal Rules of Civil Procedure, that Plaintiff be named as Representative of the Class, that the undersigned be named as Class Counsel, and direct that notice of this action be given to Class members;

B. That the Court enter an order declaring that AMAG's actions, as set forth in this Complaint, violate the state laws set forth above;

C. That the Court award Plaintiff and Class members damages, treble damages, punitive damages, and/or restitution in an amount to be determined at trial;

D. That the Court issue appropriate injunctive and other equitable relief against AMAG, including but not limited to disgorgement of monies gained as a result of its unlawful conduct;

E. That the Court award Plaintiff pre- and post-judgment interest;

F. That the Court award Plaintiff her costs of suit, including reasonable attorneys' fees and expenses, including costs of consulting and testifying experts; and

G. That the Court award any and all such other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all claims so triable.

Dated: January 13, 2020

Respectfully submitted,

KERSHAW, COOK, & TALLEY

/s/ Stuart C. Talley

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Counsel for Plaintiff and Proposed Class

DECLARATION OF STUART C. TALLEY

PURSUANT TO CALIFORNIA CIVIL CODE § 1780(d)

I, Stuart C. Talley, declare as follows:

1. I submit this declaration pursuant to section 1780(d) of the California Consumers Legal Remedies Act. I have personal knowledge of the matters set forth below and if called as a witness could and would be competent to testify thereto.

2. Defendant AMAG PHARMACEUTICALS, INC. is a Delaware corporation headquartered in Waltham, Massachusetts. Defendant AMAG PHARMACEUTICALS, INC. was engaged in the business of sales, marketing, and distribution of the drug Makena in California, and throughout the United States of America.

I declare under the penalty of perjury under the laws of the State of California and the United States that the foregoing is true and correct and that this declaration was executed on January 13, 2020 in Sacramento, California.

/s/ Stuart C. Talley
STUART C. TALLEY